Version:1.0

SCIENCES

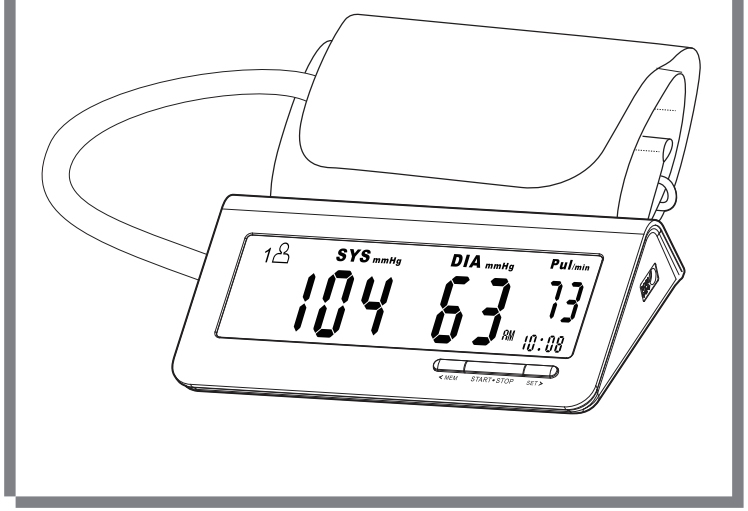
WWW.ICSCIENCES.COM

User Manual

IC Sciences Blood Pressure Arm Cuff Monitor

TMB-1018-BT

Arm Type



- Thank you for selecting the IC Sciences Blood Pressure Arm Cuff Monitor TMB-1018-BT.
- Please read the user manual carefully and thoroughly to ensure safe usage of this product, and keep the manual available for future reference.

Download and install My BP Coach from iTunes Store or Google play

App Store | Google play

Bluetooth SMART Contains FCC ID: OU9AW8001-LS

Manufactured for
Informed Clinical Sciences Corporation
1 Joy Street
Boston, MA USA 02108
www.icsciences.com

GUANGDONG TRANSTEK MEDICAL ELECTRONICS CO., LTD
Zone A, 5/F., Investment Building, No. 12 Huizhan East Rd., Torch Development District, Zhongshan, Guangdong, 528437, China

WWW.ICSCIENCES.COM

SCIENCES

Table of Contents

INTRODUCTION 2

- General Description
- Indications For Use
- Contraindications
- Measurement Principle
- Safety Information
- LCD Display Signal
- Monitor Components

BEFORE YOU START 6

- Power Supply
- Installing and Replacing the Batteries
- Apply the Cuff
- Settings
- Select User ID
- Pair-up the Blood Pressure Monitor with Your Device

START MEASUREMENT 11

- Start Measurement

DATA MANAGEMENT 12

- Recall the Records
- Delete the Records
- Transmitting Data

INFORMATION FOR USER 14

- Tips for Measurement
- Maintenance

ABOUT BLOOD PRESSURE 16

- What are systolic pressure and diastolic pressure?
- What is the standard blood pressure classification?
- Why does my blood pressure fluctuate throughout the day?
- Why are measurements taken in hospital different from at home?
- Is the result the same when measuring on the right arm?

TROUBLESHOOTING 18

SPECIFICATIONS 19

AUTHORIZED COMPONENT 20

COMPLIED STANDARDS LIST 20

FCC STATEMENT 21

EMC GUDIANCE 21

♥ General Description

Thank you for selecting the IC Sciences Blood Pressure Arm Monitor (TMB-1018-BT). The monitor features blood pressure measurement, pulse rate measurement and the data storage. The design provides you with two years of storage.

Readings taken by the TMB-1018-BT are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step-by-step instruction for using the product.

Read the manual thoroughly before using the product.

Features:

- Blue LCD display with white backlight
- Up to 60 pieces of recorded data stored for each user
- Measuring While Inflating (MWI) technology
- Bluetooth data transmitting function

♥ Indications For Use

1.The IC Sciences Blood Pressure Arm Monitor is a digital monitor intended for measuring blood pressure and heartbeat rate for people with an arm circumference ranging from 22cm to 42 cm (about 8.66-16.5 inches).

2. The monitor detects irregular heartbeats during measurement and gives a warning signal with readings.

3. It is intended for adult use in the home setting only.

♥ Contraindications

1. The device is contraindicated for any person connected to a wearable or implantable electronic device or instrument such as a pacemaker or defibrillator.

2. The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

♥ Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure.Then it starts inflating the arm cuff; meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure and pulse rate.The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation.The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals over.

♥ Safety Information

The symbols below might be in the user manual, on labeling, or other components.

	Symbol for “THE OPERATION GUIDE MUST BE READ”		Symbol for “TYPE BF APPLIED PARTS”
	Symbol for “MANUFACTURE DATE”		Symbol for “ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please follow local guidelines.”
	Symbol for “MANUFACTURER”		Symbol for “DIRECT CURRENT”
SN	Symbol for “SERIAL NUMBER”		Symbol for “Including RF transmitter”
Bluetooth SMART	The Bluetooth Combination Mark		

CAUTION

Please read this user manual carefully and thoroughly before use.

This device is intended for adult use in the home/domestic only.

This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the upper arm or for functions other than obtaining a blood pressure measurement.

Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not start or end medical treatment without a physician’s consent.

If you are taking medication, consult your physician to determine the most appropriate time for your measurement. Never change a prescribed medication without your physician’s consent.

This unit is not suitable for continuous monitoring during medical emergencies or operations.

If the pressure of the cuff exceeds 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when its pressure exceeds 40 kPa (300 mmHg), detach the cuff from the upper arm and press the homologous button to stop inflation.

Do not use the monitor under the conditions of strong electromagnetic field (e.g. mobile) that radiates interference signal or electrical fast transient / burst signal, especially when the AC adaptor is applied.

Do not touch the output of batteries and the patient simultaneously.

The device is not AP/APG equipment. It is not suitable for use in the presence of a flammable anesthetic mixture with air (or oxygen, nitrous oxide).

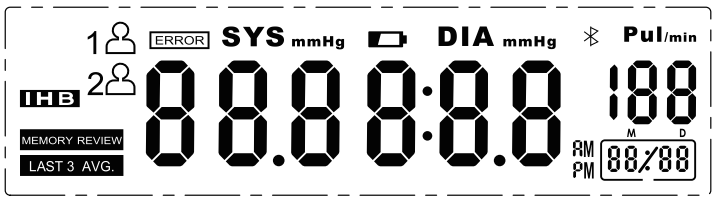
Please keep the unit out of reach of infants or children, since inhalation or swallowing of small parts is dangerous or even fatal.

Please use ACCESSORIES and detachable parts specified / authorised by IC Sciences. Otherwise, it may cause damage to the unit or danger to the user / patient.

The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5: 2009 and ISO 10993-10:2010. It will not cause any potential alergic reaction or contact injury.

Please make sure the unit functions safely and it is in proper working conditions before use.

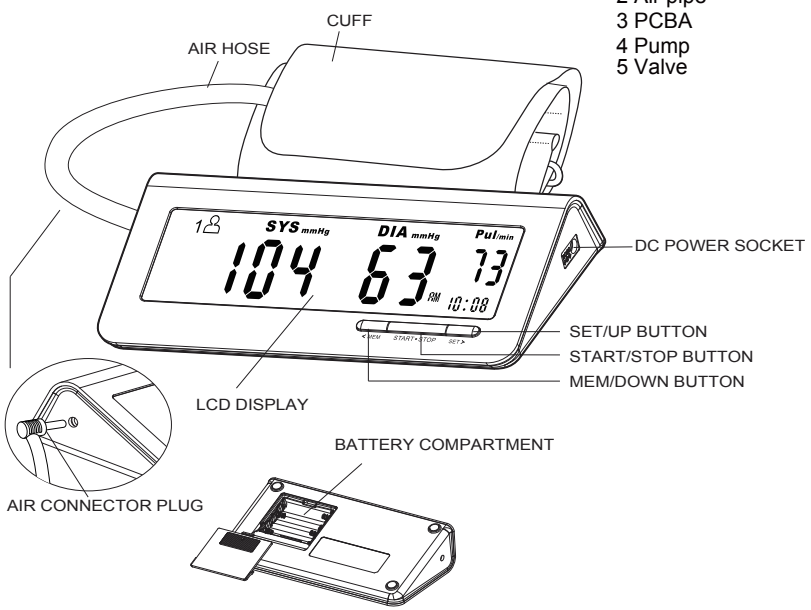
♥ LCD Display Signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic Blood Pressure	Top number
DIA	Diastolic Blood Pressure	Bottom number
Pul/min	Pulse	beat/minute
1	User 1	Start measurement for user 1, save and transmit the measuring result automatically.
2	User 2	Start measurement for user 2, save and transmit the measuring result automatically.
MEMORY REVIEW	Memory Review Mode	Indicate the current mode is memory review mode, and which group of memory it is.
	Successful Bluetooth Connection	Bluetooth is turned on.
LAST 3 AVG.	Average Value	Average value of latest three records.
ERROR	Error	The monitor detects error.
	Low Battery	Low battery; replace the batteries.
mmHg	Unit	Measurement unit of blood pressure
	Current Time	Month:Day (Hour:Minute)
IHB	Irregular Heartbeat Detector	Detects irregular heart beats.

♥ Monitor Components

Component list of pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve

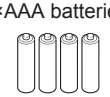


♥ List

1.Blood Pressure Monitor (TMB-1018-BT)

2.Cuff (Type BF Applied Part) (22cm-42cm)
(Please use IC Sciences' authorized cuff)

3. 4×AAA batteries



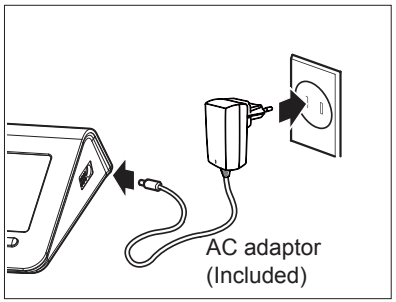
4.User manual

♥ Power Supply

1.Battery powered mode:
6VDC 4×AAA batteries

2.AC adaptor powered mode:
6V ⎓ 1A
(Can be supplied by AC adaptor model UE08WCP-060100SPA) (Included)

Please unplug the adaptor to use battery power.

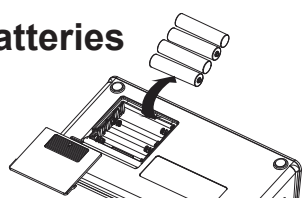


CAUTION

In order to get the best effect and protect your monitor, please use the battery and power adaptor, which complies with U.S. safety standard.

♥ Installing and Replacing the Batteries

1. Open the battery door.
2. Insert the batteries according to the polarity indications.
3. Close the battery door.



Replace the batteries under following circumstances:

- Lo displays on the LCD.
- The LCD display dims.
- When powering on the monitor, the LCD doesn't light up.

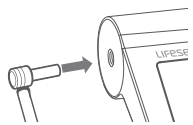
CAUTION

- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

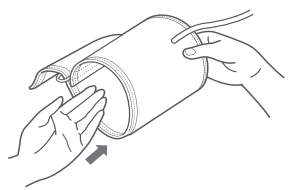
♥ Download and install My BP Coach from iTunes App store or Google play

♥ Apply the Cuff

1.Insert the plug of cuff's air pipe into the interface located on the right side of the monitor.

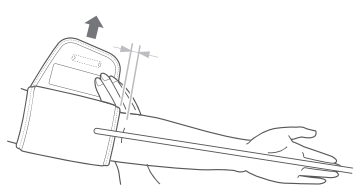


2.As pictured on the right, position the cuff on your upper arm.



3.Tighten the cuff. Make sure the cuff is fixed 2 to 3 centimeters (about an inch) above your elbow.

You should be able to insert one finger when the cuff is tightened around your upper arm.



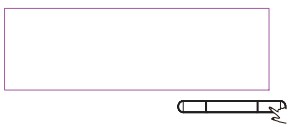
4.Correct Posture:
It is best to position the cuff on your bare arm.
Sit comfortably and relaxed in a chair. The center of the cuff should be about even with your heart.
Sit with legs relaxed with your feet falling outwards. Rest your arm on a table with your palm facing up.

♥ Settings

Set the time on your arm cuff before your initial use to ensure each record is labeled with a time stamp. (The range of the year is 2000 to 2050. Time Format: 12 Hours)

NOTE: The monitor will shut off 60 seconds after the last operation when in Setting Interface.

1.When the monitor is OFF, press and hold SET button to enter [HOUR] and [MINUTE] setting.



2.Press MEM button to change the numeral. Each press will increase the numeral by one in a cycling manner.

HOUR

3.Press SET button to confirm the [HOUR] and [MINUTE]. Then the monitor diverts to [MONTH] and [DAY] setting.

MINUTE

4.Repeat step 2 and 3 to confirm [MONTH] and [DAY]. Then the monitor switches to [YEAR] setting.

MONTH

DAY

5.Repeat step 2 and 3 to confirm [YEAR].

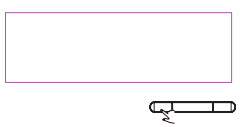
YEAR

6.After confirming the [YEAR], the LCD will display “dOnE” and the monitor will shut off.

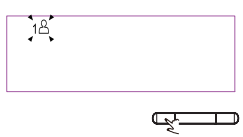
♥ Select User ID

NOTE: The monitor will shut off 60 seconds after the last operation when in User ID selection mode.

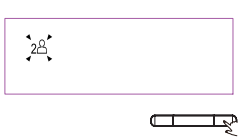
1.When the monitor is OFF, press and hold MEM button to enter User ID selection mode.



2.The current User ID blinks.



3.Press MEM button to switch between User 1 and User 2.



4.Press SET button to confirm the selected User ID.

♥ Pair up the Blood Pressure Monitor with Your Device

1.Turn on Bluetooth and the My BP Coach app. Make sure both are ON when pair up is proceeding.

2.With the monitor OFF, press and hold the START•STOP button about five seconds to start pair up until the symbol [ᛒ] blinks, indicating pair up is proceeding.

If successful, symbols will be shown on the LCD like the picture on the right.

If devices fail to connect, symbols will be shown on the LCD like the picture on the right.

3.The monitor will shut off after pair up process is complete.

Bluetooth Module No.: AW2540MV1
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: -1 dBm
Supply Voltage: 2-3.6 V
Transmitting Distance: 10 meters (32 feet)

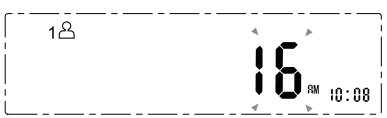
♥ Start Measurement

After correctly positioning the cuff and selecting User ID, press START·STOP button to turn on the monitor, and it will complete the measurement process. Take User 1 for example.

1.LCD display

2.Adjust to zero.

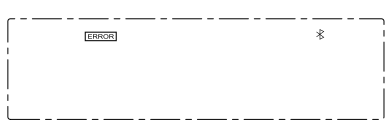
3.Inflating and measuring.



4.Display and save the result. And the result will be transmitted to the app. The icon ᛒ blinks.

If the data is successfully transmitted, the LCD will then display “dOnE”.

If the data transmission fails, the LCD will display “ ERROR” instead.



5. Press START•STOP button to turn off the monitor. Otherwise, the monitor will shut off within 1 minute after last operation.

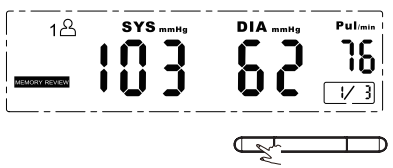
Tips:

A.Maximum 60 records are both for user 1 and user 2.

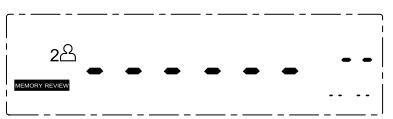
♥ Recall the Records

1.When the monitor is OFF, press MEM button to retrieve the memory. The monitor will display the average value of latest three measurements.

2.Press MEM button and SET button to rotate the records. Up to 60 records will be stored under each user ID.
The measurement date and time will be displayed alternatively.



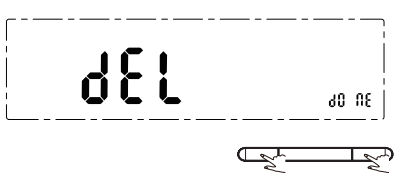
3.If you would like to check another user ID's history, please follow the instructions in Select User ID to change to another User ID first.



No Record found for User 2!

♥ Delete the Records

1.When under data enquiry mode, press and hold both MEM button and SET button for 3 seconds to clear memory. The LCD will display "dEL dOnE", indicating that the memory is cleared.



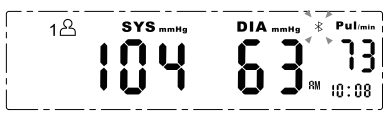
♥ Transmitting Data

Manual Data Transmission

With the advanced Bluetooth 4.0 technology applied, the mobile or portable equipments, which are equipped with Bluetooth function in line with BLE Technical Specifications as well as BLP Protocol established by global organization Bluetooth SIG, are capable to receive your personal health data.

When both the My BP Coach app and Bluetooth are ON, TMB-1018-BT will automatically transmit measurement data to your smartphone via Bluetooth.

1. After measurement, the symbol ᛒ lights up, indicating the measuring result is being automatically transmitted to smartphone.



2.If successful, the LCD will display "dOnE".

3.If the devices fail to connect, the LCD will display "ERROR".

CAUTION

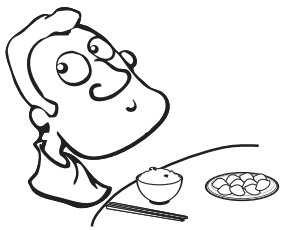
- Interference may occur in the vicinity of equipment marked with the following symbol . And TMB-1018-BT may interfere other electrical equipment in the area.
- Sensitive people, including pregnant women and those with implanted medical electronic devices, should avoid using the unit whenever possible.
- Keep the monitor at least 20 centimeters (about 8 inches) away from the human body (especially the head) when the data transmission is proceeding after measurement.
- To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

1. The range between the device and BT end should be reasonably close, from 1 meter to 10 meters (about 3 to 30 feet). Please ensure no obstacles are between the device and BT end to obtain a connection and to lower the RF output range.
2. To avoid interference, other electronic devices (particularly those with wireless transmission/Transmitter) should be kept at least 1 meter (about 3 feet) away from the monitor.

♥ Tips for Measurement

Your readings may be innaccurate if the measurement is taken in the following circumstances:



Within 1 hour
after dinner or drinking

Immediately measuring
after tea, coffee, smoking

Within 20 minutes
after taking a bath

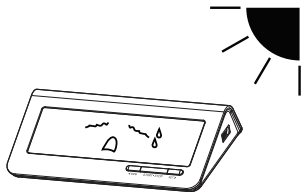
When talking or moving your fingers

In a very cold environment

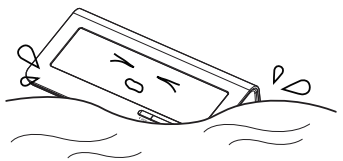
When you need to urinate

♥ Maintenance

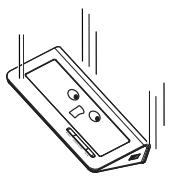
To obtain the best performance, please follow the tips below:



Use and store in a dry place and
avoid the sunshine



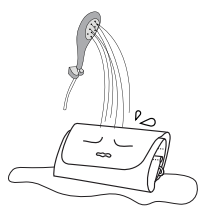
Avoid immersing in water.
Clean with a dry cloth.



Avoid shaking and dropping.

Avoid dusty environment and
unstable temperatures

Use a slightly damp cloth
to remove the dirt.



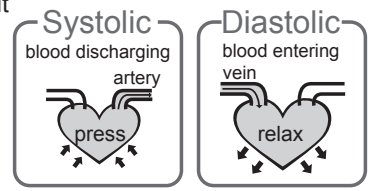
Avoid washing the cuff

CAUTION

1. Make sure the unit functions safely and is in proper working order before use. Don't service or maintain while the device is in use.
2. If you have any problems with this device, such as setting up, maintaining or using, please contact IC Sciences. Do not open or repair the device yourself.
3. Please contact IC Sciences if any unexpected operation or events occur.
4. Cleaning: Dusty environments may affect the performance of the unit. Please use a soft cloth to remove dirt from the device and cuff before and after use.
5. Calibration: The manufacturer does not require such preventive inspections or calibration by other persons and will make available on request of circuit diagrams, component part list, etc.
6. Disposal: Degraded sensors may result in inaccurate measurement while loosened electrodes may cause the monitor's failure to power on. Please dispose of ACCESSORIES, detachable parts, and ME EQUIPMENT according to local guidelines.

♥ What are systolic and diastolic pressures?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ What is the standard blood pressure classification?

The chart on the right illustrates the blood pressure classification mode by American Heart Association (AHA).

The AHA recommends the following guidelines for upper limit of normal blood pressure readings at home.

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

AHA Home Guideline for Upper Limit of Normal BP	
Systolic Blood Pressure	135 mm Hg
Diastolic Blood Pressure	85 mm Hg

♥ Irregular Heartbeat Detector

This Blood Pressure Monitor is equipped with an intelligent function of Irregular Heartbeat (IHB) Detector. During each measurement, the arm cuff records the heartbeat intervals and determines the standard deviation. If the calculated value is larger than or equal to 15, this monitor will show the IHB symbol on the screen when displaying the measuring result.

CAUTION

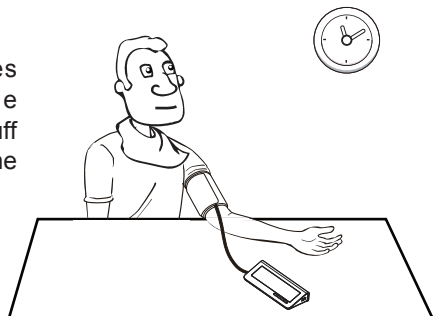
The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies throughout the day. It can also be affected by the way you fasten your cuff and your measurement position; take the measurement in the same position.

2.Blood pressure varies even more when you on medication.

3.Wait at least 3 minutes to take your blood pressure again.



♥ Why are measurements taken in the hospital different than those taken at home?

Blood pressure can be different even during a 24-hour period because of the weather, emotion, exercise etc. Especially “white coat” syndrome, which makes results higher than the ones at home.

Follow these tips for correct to ensure correct readings:

Make sure the cuff is fastened correctly.

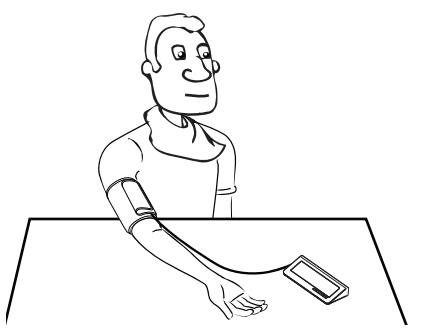
Make sure the the cuff is not too tight or too loose.

Relax for 4-5 minutes before taking your blood pressure.

Take several deep breaths before beginning.

♥ Is the result the same when measuring on the right arm?

It is ok to take readings in both arms, but there may be different results for each arm. Try to use the same arm every time.



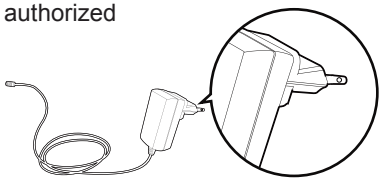
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or display +LO	Batteries are low.	Replace with new batteries
Error massage	ERROR shows	Data communication has failed	Check if the APP is on or not, try data transmission again.
	Error 1 shows	Inflation is slow or the cuff is not secure.	Refasten the cuff and then measure again.
	Error 2 shows	The cuff is very tight	Readjust the cuff, not too loose or too tight and then measure again.
	Error 3 shows	The pressure of the cuff is excess.	Refasten the cuff and then measure again.
	Error 5 or Error 6 shows	System error occurred.	Retake the measurement. If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
	Error 10 or Error 11 shows	The monitor detected motion, talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	Error 20 shows	The measurement process does not detect the pulse signal.	Loosen clothing on the arm and then measure again.
	Error 21shows on the display.	The treatment of the measurement failed.	Relax for a moment and then measure again.

Power supply	Battery Powered Mode: 6V (4 x AAA-size batteries) AC Adaptor Powered Mode: 6V ⎓ 1A (Can be supplied by AC adaptor model UE08WCP-060100SPA!) (Included)
Display mode	Blue LCD with White Backlight V.A. = 140mm(L) x 36mm(W)
Measurement mode	Oscillographic testing mode
Measurement range	Pressure: 0-40kpa(0~300mmHg) pulse value:(40-199)times/minute
Accuracy	Pressure: 5℃-40℃ within ±0.4kpa (3mmHg) pulse value: ±5%
Working condition	Temperature:5℃ to 40℃ (41 F to 104 F) Relative humidity ≤85% Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature: -20℃ to 60 ℃ (-4 F to 140 F) RH: 10% to 93% Atmospheric pressure: 50kPa to 106kPa
Measurement perimeter of the upper arm	About 22cm - 42cm (8.6 inches to 16.5 inches)
Weight	Approx. 465g (about 1 lb) (Excluding batteries)
External dimensions	Approx. 180*100*40mm (approx 7 x 4 x 1.6 in)
Attachment	4*AAA batteries,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Device Classification	Battery Powered Mode: Internally Powered ME Equipment AC Adaptor Powered Mode: Class II ME Equipment
IP Classification	IP22
Software Version	V01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. Please use the included IC Sciences authorized adaptor



Adaptor
Type: UE08WCP-060100SPA
Input: 100-240V, 50-60Hz,400mA
Output: 6V ⎓ 1A
(Conforms to UL Certification)

♥ Contact Information

For more information about our products and assistance, please contact www.icsciences.com for customer service.

Manufactured for: IC Sciences
Company: Informed Clinical Sciences Corporation
Address: 1 Joy Street
Boston, MA USA 02108

♥ Complied Standards List

Risk Management	ISO 14971:2007
Labeling	EN 980:2008
User Manual	EN 1041:2008
Generl Requirements for Safety	IEC 60601-1:2005/A1:2012
Performance and Clinical Requirements	ANSI/AAMI/IEC 80601-2-30:2009 ANSI/AAMI/ISO 81060-2:2009
Electromagnetic Compatibility	IEC 60601-1-2:2007
Software life-cycle processes	IEC 62304:2006

♥ FCC Statement

Caution: The user is cautioned that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Note:
POTENTIAL FOR RADIO/TELEVISION INTERFERENCE (for U.S.A. only)
This product has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.
The product generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If the product does cause harmful interference to radio or television reception, which can be determined by turning the product on / off, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the product and the receiver.
- Connect the product into an outlet on a circuit which is different from what the receiver is connected to.
- Consult the dealer or an experienced radio / TV technician for help.

♥ EMC guidance

Table 1 – Guidance and MANUFACTURER'S declaration – ELECTROMAGNETIC EMISSIONS – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 2	The device must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Table 2 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for all ME EQUIPMENT and ME SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 4 – Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 TEST LEVEL**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 6 – Recommended separation distances between portable and mobile RF communications equipment and the ME EQUIPMENT or ME SYSTEM – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Recommended separation distances between portable and mobile RF communications equipment and the device			
The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.333\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.690	3.690	7.378
100	11.67	11.67	23.33
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			